Filing Date: June 20, 2003

Title: SYSTEM FOR MEDICAL LEAD TUNNELING

REMARKS

This is in response to the Office Action dated October 4, 2004, and the references cited therewith.

Claims 26 and 28 are amended. Claims 1-28 are pending.

Applicant notes that Claims 27-28 were not examined in the present Office Action, but were noted to be rejected on the Office Action Summary sheet. Applicant respectfully requests allowance of claims 27-28.

§102 Rejection of the Claims

Claims 1, 3-6, 11, 13-18 and 22-25 were rejected under 35 USC § 102(e) as being anticipated by Erb et al. (U.S. Patent No. 6,436,119). Applicant notes that Erb is a reference under 102(e) and Applicant reserves the right to swear behind the reference.

Claims 1 and 3-6

Applicant traverses the rejection since the cited reference does not include each limitation recited in the claim. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Dillon 919 F.2d 688 (Fed. Cir. 1990) (en banc). Applicant believes claim 1 is not anticipated by the cited reference since Applicant cannot find in the Erb reference an elongated rod having a holding member on one end and dimensioned to fit within the elongated tube, the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube. In contrast, Erb discusses a surgical dilator having an inner rod 24 having threads 96 to attach a control cap 26. (Col. 7, lines 33-43).

The Office Action asserts that "the proximal end may hold a hypothetical lead that has a thread attached thereto to its end for pulling the lead through the tube. Function recitations directed to the specifics of a lead are given no patentable weight." Applicant traverses. The Office Action has provided no support for the "hypothetical lead that has a thread attached thereto to its end for pulling the lead through the tube." Applicant respectfully traverses this Official Notice and requests the Examiner to provide a reference that describes such subject matter. Absent a reference, it appears that the Examiner is using personal knowledge, so the Examiner is respectfully requested to submit an affidavit as required by 37 C.F.R. § 1.104(d)(2). Filing Date: June 20, 2003

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Furthermore, the Office Action has improperly refused to give patentable weight to "the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube." Applicant respectfully traverses these grounds for rejection and points out that functional language is specifically authorized by In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); In re Caldwell, 138 USPQ 243 (CCPA 1963); Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987 ("so that" functional clause of claim renders reference non-anticipating); MPEP § 2173.05(g).

Applicant notes that the lead itself is not recited as a positive limitation of the claim. However, the claim does recite a "holding member adapted to hold an end of a lead." This is a positive structural limitation, and the cited reference does not include such subject matter.

Claims 3-6 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 11 and 13-17

Claim 11 recites "a holding member adapted to hold an end of a lead to pull the lead through the elongated tube." As noted above, the Office Action has not given patentable weight to this positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Claims 13-17 depend from claim 11. Reconsideration and allowance is respectfully requested.

Claim 18

Claim 18 recites "an elongated rod having a holding member on one end, the holding member adapted to hold an end of a lead." Again, the Office Action has not given patentable weight to a positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

Claims 22-25

Claim 22 recites "an elongated rod having a lead holding member on one end." Again, Applicant cannot find in Erb anything that can be construed as a lead holding member. The Office Action has not given patentable weight to the positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

Claims 1-5, 11-15, 17-19 and 22-24 were rejected under 35 USC § 102(b) as being anticipated by Waldvogel (U.S. Patent No. 5,061,245).

Claims 1-5

Applicant traverses the rejection of claim 1 since the cited reference does not include each limitation recited in the claim. Applicant believes claim 1 is not anticipated by the cited reference since Applicant cannot find in the Waldvogel reference an elongated rod having a holding member on one end and dimensioned to fit within the elongated tube, the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube. In contrast, Waldvogel discusses an arterial bypass tool having a rod 16 having a tab 17 with apertures 18, 19, which are utilized to secure a bypass artery. (Col. 4, lines 30-35).

The Office Action asserts that "sutures are disclosed as holding graft members for pulling the graft through the tube, however the examiner considers them to be capable of attaching to a lead to pull through the tube as well." Applicant traverses. Again, the Office Action has provided no support for attaching a lead to sutures to pull a lead through the tube. Applicant respectfully traverses this Official Notice and requests the Examiner to provide a reference that describes such subject matter. Absent a reference, it appears that the Examiner is using personal knowledge, so the Examiner is respectfully requested to submit an affidavit as required by 37 C.F.R. § 1.104(d)(2).

Furthermore, the Office Action has improperly refused to give patentable weight to "the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube." Applicant notes that the lead itself is not recited as a positive

limitation of the claim. However, the claim does recite a "holding member adapted to hold an end of a lead." This is a positive structural limitation, and the cited reference does not include such subject matter.

Claims 2-5 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 11-15 and 17

Claim 11 recites "a holding member adapted to hold an end of a lead to pull the lead through the elongated tube." Again, the Office Action has not given patentable weight to this positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Claims 12-15 and 17 depend from claim 11. Reconsideration and allowance is respectfully requested.

<u>Claims 18-19</u>

Claim 18 recites "an elongated rod having a holding member on one end, the holding member adapted to hold an end of a lead." Again, the Office Action has not given patentable weight to the positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Claim 19 depends from claim 18. Reconsideration and allowance is respectfully requested.

Claims 22-24

Claim 22 recites "an elongated rod having a lead holding member on one end." Again, Applicant cannot find in Waldvogel anything that can be construed as a lead holding member. The Office Action has not given patentable weight to the positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Claims 23-24 depend from claim 22. Reconsideration and allowance is respectfully requested.

Claims 1, 8-10, 11 and 20-22 were rejected under 35 USC § 102(b) as being anticipated by Clarke (U.S. Patent No. 3,871,379).

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Claims 1, 8-10, and 11

Applicant traverses the rejection of claim 1 since the cited reference does not include each limitation recited in the claim. Applicant believes claim 1 is not anticipated by the cited reference since Applicant cannot find in the Clarke reference an elongated rod having a holding member on one end and dimensioned to fit within the elongated tube, the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube. In contrast, Clarke discusses a laparoscopy tool including forceps having links 18 and 19 and jaws 34, 35, to grip tissue or a suture. (Col. 4, lines 9-38).

The Office Action asserts that the "biased jaws of the forceps are capable of tunneling through tissue and have serve as a gripping means. A hypothetical lead having a suture at a distal end could be pulled backed through the catheter 14." Applicant traverses. Again, the Office Action has provided no support for attaching a lead to sutures and pulling the lead with forceps. Applicant respectfully traverses this Official Notice and requests the Examiner to provide a reference that describes such subject matter. Absent a reference, it appears that the Examiner is using personal knowledge, so the Examiner is respectfully requested to submit an affidavit as required by 37 C.F.R. § 1.104(d)(2).

Furthermore, the Office Action has improperly refused to give patentable weight to "the holding member adapted to hold an end of a lead such that the end of the lead can be pulled through the elongated tube." Applicant notes that the lead itself is not recited as a positive limitation of the claim. However, the claim does recite a "holding member adapted to hold an end of a lead." This is a positive structural limitation, and the cited reference does not include such subject matter.

Claims 8-10 and 11 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 20-21

Claims 20-21 depend from parent claim 18. Claim 18 recites "an elongated rod having a holding member on one end, the holding member adapted to hold an end of a lead." Again, the Office Action has not given patentable weight to the positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

Claim 22

Claim 22 recites "an elongated rod having a lead holding member on one end." Again, Applicant cannot find in Clarke anything that can be construed as a lead holding member. The Office Action has not given patentable weight to the positive structural limitation, and the discussion above for claim 1 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

Claim 26 was rejected under 35 USC § 102(b) as being anticipated by Bonner et al. (U.S. Patent No. 5,902,331).

Applicant has amended claim 26 to better describe the subject matter recited in the claim. Applicant believes claim 26 is not anticipated by the cited reference since the reference does not include each limitation recited in the claim. For instance, Applicant cannot find in Bonner "pulling an end of a lead through the elongated tube by pulling an elongated rod through the tube with the end of the lead mounted to a lead holding member on an end of the elongated rod," as recited in claim 26. In contrast, Bonner discusses a lead delivery mechanism for transvenously delivering a lead. The Bonner device includes a lead pusher 60 used to push a lead transvenously to an implantation site. (Col. 12, lines 22-26). Reconsideration and allowance is respectfully requested.

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§103 Rejection of the Claims

Claim 7 was rejected under 35 USC § 103(a) as being unpatentable over Erb et al. (U.S. Patent No. 6,436,119) in view of Waldvogel (U.S. Patent No. 5,061,245) and Clarke (U.S. Patent No. 3,871,379). Applicant traverses. Claim 7 depends from claim 1 and is not obvious in view of the cited references since none of the cited references include the subject matter of the parent claim, as discussed above. Moreover, the Office Action is taking Official Notice of subject matter not discussed in any of the cited references. Applicant respectfully traverses this Official Notice and requests the Examiner to provide a reference that describes such subject matter. Absent a reference, it appears that the Examiner is using personal knowledge, so the Examiner is respectfully requested to submit an affidavit as required by 37 C.F.R. § 1.104(d)(2).

Claims 23-24 were rejected under 35 USC § 103(a) as being unpatentable over Bonner et al. (U.S. Patent No. 5,902,331). Applicant notes that claims 23-24 depend from claim 22. Applicant believes claims 23-24 are not obvious in view of the cited reference since the reference does not include each limitation recited in the parent claim. For instance, Applicant cannot find in Bonner an elongated rod having a lead holding member on one end and a handle on a second end, the elongated rod dimensioned to fit within an elongated tube such that the lead holding member extends from a first end of the elongated tube and the handle extends from a second end of the elongated tube, the lead holding member adapted to hold an end of the lead located outside the first end of the elongated tube such that the end of the lead can be pulled through the elongated tube to exit on the second end of the elongated tube. Reconsideration and allowance is respectfully requested.

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Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this day of January, 2005.

Name

Signature